

Applicant : Robert N. Hamlin
Serial No. : 08/692,314
Filed : August 5, 1996
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Attorney's Docket No.: 10527-003005 / PC7558D-U.S.

REMARKS

Claims 206, 208, 210, 211, 213 and 218 have been amended. Claims 219 and 220 have been added. Claim 220 is an independent claim including the subject matter of claim 215, which the examiner indicated was allowable. Applicant submits claim 220 should be allowed. Claim 206 is the only other independent claim.

Claim 206 stands rejected under the 35 U.S.C. §112, first paragraph written description requirement. The rejection reasons that claim 206 is generic to a medical balloon having PEEK or PEK in an inner or outer layer. But, according to the rejection, the specification describes these materials as suitable for a tensile layer and the tensile layer is external to an inner layer.

Reconsideration is once again requested.

The Examiner's attention is directed to Lampi Corp. v. American Power Products, Inc., 228 F.3d 1365 (Fed. Cir. 2000), a copy of which is enclosed for the Examiner's convenience. There the invention was directed to a lamp having a housing made of "half-shells". Id. The issue was whether the specification supported only the identical half-shells or a more generic construction including non-identical half shells. Id. at 1378. While the specification illustrated and described particular advantages of identical half-shells, the court found a generic construction permissible because the specification was not narrowly tailored to preclude non-identical half-shells:

In order to satisfy the written description requirement, the disclosure as originally filed need not provide in haec verba support for the claimed subject matter at issue. See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 U.S.P.Q.2d (BNA) 1895, 1904 (Fed. Cir. 1996). The requirement is met if "the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co. Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985) (internal quotations omitted).

* * *

We conclude that the district court's finding on the written description issue did not constitute clear error. The specification of the '875 patent twice refers to "identically shaped" or "identical" half-shells. See '875

patent, col. 2, ll. 19-20 ("both half-shells are identically shaped"); col. 3, l. 30 (referring to an "identical half-shell"). Contrary to APP's position, however, identical half-shells are only a preferred embodiment of the invention. The '875 patent states:

So that the housing can be easily assembled, the fluorescent lamp tube easily replaced, the wiring required to operate the fluorescent lamp installed during fabrication and, following operation of the fluorescent lamp, repaired if necessary, the housing preferably consists of two separate half-shells. To enable particularly easy and cost-effective manufacture of these two half-shells and to ensure especially easy assembly, and, in particular, by technically inexperienced individuals, both half-shells are identically shaped so that they are interchangeable. '875 patent, col. 2, ll. 11-21. It is a familiar principle of patent law that a claim need not be limited to a preferred embodiment. See *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865, 9 U.S.P.Q.2D (BNA) 1289, 1299 (Fed. Cir. 1988). The specification also includes references to half-shells without the modifier "identical" or "identically shaped," see '875 patent, col. 2, ll. 28, 32, indicating that identical half-shells are not critical to the invention. Although the patent drawings show only identical half-shells, see '875 patent, col. 3, ll. 29-30 ("Fig. 1 [showing the same embodiment as in Figs. 2 and 3] shows ... a half-shell ... together with a second, identical half-shell"), that does not compel the conclusion that the written description of the '875 patent is no narrowly tailored as to preclude Lampi from claiming non-identical half-shells in the '227 patent. Cf. *Tronzo v. Biomet, Inc.*, 145 F.3d 1154, 1159, 47 U.S.P.Q.2D (BNA) 1829, 1834 (Fed. Cir. 1998) (concluding that specification of parent application was so specific as to a particular shape of component in invention that it could not support subject matter that was generic as to shape, as claimed in later-filed application). The drawings in the patent are merely a "practical example" of the invention. See '875 patent, col. 3, l. 19. The district court therefore did not commit clear error in finding that the written description of the '875 patent was sufficient to support half-shells that are not identical, as claimed in the '227 patent.

Likewise here, while the specification refers to PEEK or PEK as polymers suitable for a tensile layer, and there may be certain advantages if the tensile layer is disposed outward of a bonding layer, the specification is not so narrowly tailored to preclude a broader claim. In fact, the specification expressly contemplates embodiments beyond the preferred examples:

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MULTILAYER EXTRUSION OF ANGIOPLASTY BALLOONS BACKGROUND OF THE INVENTION

I. Field of the Invention

This invention relates generally to balloon catheters, and more particularly to a method for fabricating a multi-layer balloon composite exhibiting enhanced characteristics attributable to the properties of the individual layers. (specification, page 1)

* * *

SUMMARY OF THE INVENTION

The above-listed desirable characteristics are achieved in accordance with the present invention by forming a multi-layer balloon where the individual layers afford a desirable property to the composite. It has been found that a layer of medium or relatively high melt temperature material which also exhibits high tensile strength with relatively low distensibility can be used to provide the required high burst or tensile strength and low radial expansion at high pressures required by the expander member in a composite structure. This layer may be referred to as the tensile layer or tensile ply. It may be a biaxially-oriented film of relatively high crystallinity. (specification, page 2)

* * *

It will be appreciated that the particular combination chosen would depend on the particular application and particular catheter involved, and that an array of multilayer expanders of different composition combinations particularly applicable to different situations can be produced. In addition, specific properties required for addressing a specific stenosis could be utilized to produce a tailor-made expander. (specification, page 4)

* * *

Similarly, in the parent to the present application, (USSN 411,649, filed September 25, 1989), specific materials in specific combinations are merely examples (emphasis ours):

SUMMARY OF THE INVENTION

The above-listed desirable characteristics are achieved in accordance with the present invention by forming a multi-layer balloon where the individual layers afford a desirable property to the composite. More particularly, a tubular parison is first generated in a co-extrusion process whereby different polymeric materials

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are coaxially layered. Subsequently, the parison is inserted in a blow molding fixture, allowing the tube to be longitudinally drawn and radially expanded until the composite film is oriented, the maximum O.D. of the expander member is defined and a desired film thickness is achieved. For example, in forming the parison, PET of a predetermined viscosity may be coextruded and where polyethylene in forming the parison and where the polyethylene lines the lumen thereof. When the expander member is formed from the parison in the blow molding operation, the PET layer affords the desired burst strength and limited radial expansion characteristic while the polyethylene layer enhances the ability to bond the resulting balloon to the catheter body. (parent specification, pages 2-3)

Finally, as pointed out in the last response, a particular material, PVC, is described as useful in either tensile layer or a bonding layer. The rejection notes that, as a tensile layer, PVC is described in combination with ABS. But this does not negate the exemplary disclosure of the same polymer in the tensile or bonding layer. As a result, to limit the claims to specific layers in specific order and having specific polymers is inconsistent with the teaching in the specification.

Applicants submit that the rejection unduly narrowly reads the specification to limit the claims to a particular preferred embodiment. As a result, the rejection does not consider what the specification conveys to a person of ordinary skill in the art.

Allowance is requested.

Enclosed is a Petition for Extension of Time fee and the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

206. (Amended) A medical balloon catheter comprising
a multilayer balloon having

an extruded [tensile] first layer comprising a first polymeric material selected
from a group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and
a second extruded layer comprising a second polymeric material different from
the first polymeric material.

208. (Amended) The medical balloon catheter of claim 207 wherein the [tensile] first
layer consists essentially of polyetheretherketone (PEEK).

210. (Amended) The medical balloon catheter of claim 209 wherein the [tensile] first
layer consists essentially of polyetherketone (PEK).

211. (Amended) The medical balloon catheter of claim 206 wherein the balloon is the
product of coextruding the [tensile] first and second layers.

213. (Amended) The medical balloon catheter of claim 206 wherein the [tensile] first
layer is biaxially oriented.

218. (Amended) The medical balloon of claim 206, wherein the [tensile] first layer is
an outer layer of the balloon.